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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,006	01/07/2002	Lothar Eggeling	PT 1.1678	7184
23416	7590	04/26/2006	EXAMINER	
CONNOLLY BOVE LODGE & HUTZ, LLP			FRONDA, CHRISTIAN L	
P O BOX 2207			ART UNIT	
WILMINGTON, DE 19899			PAPER NUMBER	

1652

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,006	Applicant(s) EGGELING ET AL.	
	Examiner Christian L. Fronda	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26, 29-37 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-26, 29-37 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/23/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 14-26, 29-37, and 40 are pending and under consideration in this Office Action.
2. The rejection of claims 14-26, 29-37, and 40 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of applicants' amendments and arguments filed on 01/23/2006.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 14-26, 29-37, and 40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated microorganism transformed with a polynucleotide comprising SEQ ID NO: 1 and SEQ ID NO:2, and a method for producing L-valine using said isolated microorganism; does not reasonably provide enablement for any other embodiment as recited in the claims.

Applicants' arguments filed 01/23/2006 have been fully considered but are not persuasive. Applicants' position is that undue experimentation is not undue since the instant specification provides guidance for isolating genes using functional complementation and that persons of skill in the art can use known *ilvD* and *ilvBNC* sequences as probes as illustrated by the cited references of DeRossi et al. and Gusberty et al. attached to the instant amendment dated 01/23/2006. The examiner appreciates applicants' arguments but respectfully disagrees for reasons of record as supplemented below.

As stated in the previous Office Action, the specification provides guidance for a dihydroxy acid dehydratase (*ilvD*) of SEQ ID NO: 2 encoded by SEQ ID NO: 1, ketopantoate hydroxymethyl transferase of SEQ ID NO: 4 encoded by SEQ ID NO: 3, and pantothenate ligase of SEQ ID NO: 5 encoded by SEQ ID NO: 3 from *Corynebacterium glutamicum*. The examiner takes the position that the instant specification only provides guidance for methods for isolating polynucleotides using functional complementation or using known *ilvD* and *ilvBNC* (acetohydroxy acid synthase and isomeroreductase) sequences as probes. However, the specification does not provide guidance, prediction, and working examples for the recited species

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of *Corynebacterium* transformed with any polynucleotide encoding ilvD and/or ilvBNC enzymes other than the above mentioned polynucleotides encoding the enzymes consisting of the amino acid sequences of SEQ ID NO:s 2, 4, and 5, respectively.

Thus, an undue amount of trial and error experimentation must be preformed where such experimentation involves searching and screening a vast number of biological sources for polynucleotides encoding any ilvD and ilvBNC enzymes to be transformed into any species of *Corynebacterium*. Trial and error experimentation must then be performed to ascertain whether transforming any species of *Corynebacterium* with polynucleotides encoding any ilvD and/or ilvBNC enzymes will enable that organism to over produce L-valine. The examiner maintains that general teaching regarding screening and searching for the claimed product and method of using the claimed product, such as functional complementation or screening with probes from known sequences, is not guidance for making the claimed invention.

Amending the claims to recite the specific SEQ ID NOs of the recited ilvD and ilvBNC enzymes may overcome the rejection.

Conclusion

5. No claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.


7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


TEKCHAND SAIDHA
PRIMARY EXAMINER